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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/783,896	02/15/2001	Mark I. Greene	PENN-0743	3799

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EXAMINER
TUNG, JOYCE

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/783,896	Greene et al.
Examiner	**Art Unit**
Joyce Tung	1637

-- ***The MAILING DATE of this communication appears on the cover sheet with the correspondence address*** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above, claim(s) *2-10* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1 and 11-14* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-14* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1637.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1 and 11-14, drawn to a method for detecting molecule expressing a selected epitope in a sample, classified in class 435, subclass 91.2.

   II. Claims 2-3 and 5-6, drawn to a kit for the detection of molecules expressing a selected epitope via fluorescence and for profiling proteins in a cell lysate, classified in class 435, subclass 810.

   III. Claim 4, drawn to a method for profiling proteins in a cell lysate, classified in class 435, subclass 92.51.

   IV. Claims 7-8, drawn to a method for developing a two-component system in vitro, classified in class 435, subclass 91.5.

   V. Claims 9-10, drawn to a method for interacting of molecules *in vitro*, classified in class 435, subclass 91.5.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II, and I, III and IV are related as product and process of use. The inventions can be

shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, Invention II, claims 2-3 and 5-6 can be used in immunoassay.

3. Inventions I, III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, Invention I is drawn to a method for detecting molecule expressing a selected epitope in a sample, Invention III is drawn to a method for profiling proteins in a cell lysate and Invention IV is drawn to a method for developing a two-component system and Invention V is drawn to a method for interacting of molecules *in vitro*. Based upon the different functions of the preamble, they are inherent that there are different method steps involved to perform the method. Therefore, they are patentable distinct.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Ms. Jane Massey on 12/3/2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1 and 11-14. Affirmation of this election must be made by applicant in replying to this Office action.

Claims 2-10 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

7. The title of the invention is not descriptive because the old title is directed to method for immuno-detection of epitopes on molecules and for detection of interactions of molecules via fluorescent dyes, while the claim language is directed to a method of detecting molecules expressing a selected epitope via fluorescent dyes. A new title is required that is clearly indicative of the invention to which the claims are directed.

Information Disclosure Statement

8. The references AB and AH lined through were not considered because the references were not provided in the application. The submission of the copy of the references is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 11-14 are vague and indefinite because the language "the amplified oligonucleotide" in step 9(d) of claim 11 has no antecedent basis. Since the epitope detector comprises an oligonucleotide and the oligonucleotide of said epitope is amplified in step (c), it is unclear whether or not the amplified oligonucleotide in step (d) is the amplified oligonucleotide of said epitope in step (c). Clarification is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al. (Jpn. J. Cancer Res. Vol. 86, pg. 885-889).

Suzuki et al. disclose a method for detecting molecules expressing a selected epitope in a sample comprising:

(a) immobilizing a molecule expressing a selected epitope in a sample to a selected surface (See pg. 885, the Abstract);

(b) contacting the surface with an epitope molecules on the surface, said epitope detector comprising an oligonucleotide attached to a monoclonal antibody for the selected epitope (See pg. 885, the Abstract);

© amplifying the oligonucleotide of said epitope detector (See pg. 885, the Abstract);

(d) contacting the amplified oligonucleotide with a fluorescent dye which stains the oligonucleotide and

(e) measuring fluorescence emitted from the stained oligonucleotide which is indicative of epitope detector bound to the surface and molecule expressing the selected epitope in the sample (See pg. 887, column 1, fig.1).

Thus the teachings of Suzuki et al. anticipate the limitations of claim 1.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al. (Jpn. J. Cancer Res. Vol. 86, pg. 885-889) in view of Eberwine et al. (5,922,553) and Zeytinoglu et al. (5,874,226).

Suzuki et al. disclose a method for detecting molecules expressing a selected epitope in a sample comprising:

(a) immobilizing a molecule expressing a selected epitope in a sample to a selected surface (See pg. 885, the Abstract);

(b) contacting the surface with an epitope molecules on the surface, said epitope detector comprising an oligonucleotide attached to a monoclonal antibody for the selected epitope (See pg. 885, the Abstract);

© amplifying the oligonucleotide of said epitope detector (See pg. 885, the Abstract);

(d) contacting the amplified oligonucleotide with a fluorescent dye which stains the oligonucleotide and

(e) measuring fluorescence emitted from the stained oligonucleotide which is indicative of epitope detector bound to the surface and molecule expressing the selected epitope in the sample (See pg. 887, column 1, fig.1).

Zusuki et al. do not disclose step (d) of claim 11.

Eberwine et al. disclose a transcriptase based reaction to increase sensitivity and detecting the amplified oligonucleotide (See column 2, lines 37- 51).

Eberwine et al. also disclose quantifying the amplified oligonucleotide detected in step (e) of claim 11 (See column 7, claim 1) and that the selected surface to which the molecule expressing a selected epitope in a sample is immobilized is a chip or plastic well (See column 4, lines 17-36).

None of the references above disclose there are two steps involved in the method as claimed.

Zeytinoglu et al. disclose in situ immunodetection of antigens involving polymerase chain reaction (See column 1, lines 36-54) and other amplification technologies are applicable, including two steps (See column 5, lines 14-16).

It would have been prima facie obvious to an ordinary skill in the art at the time of the instant invention to modify the method of Zusuki et al. by adding an additional step which is transcriptase based reaction as taught by Eberwine et al. and Zeytinoglu et al.. The motivated is that the method of Eberwine et al. can be most effective for the detection of rare messages (See column 3, lines 9-10) and Zeytinoglu et al. disclose that the PCR amplification method shown is

especially advantageous where the amount of antigen to be detected is very small, e.g., 500 molecules. Thus, an ordinary skill in the art would have added an additional step of amplification to obtain the enough amount of signal for detection.

15. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1656 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

February 14, 2002

GARY BENZION, PH.D
SUPERVISORY PATENT EXAMINER
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